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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/312,351

05/14/1999

JON A. WOLFF

MIRUS.006

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07/13/2006

MIRUS CORPORATION
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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/312,351	Applicant(s) WOLFF ET AL.	
	Examiner Joseph T. Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-11 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 20, 2006 has been entered.

DETAILED ACTION

This application claims benefit to provisional application 60/085,764, filed May 16, 1998.

Applicants' amendment filed April 20, 2006 has been received and entered. The specification has been amended. Claims 1-6, 12-18, 24-28 have been canceled. Claims 7 and 19 have been amended. Claims 7-11, 19-23 are pending and currently under examination.

Specification

The nucleotide sequence disclosure contained in this application complies with 37 CFR 1.821(d).

The amendment to the specification has addressed the basis of the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

Claims also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described is withdrawn.

Claims 24-28 have been canceled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 17 recites the limitation "the electron withdrawing group" in the second line of step (b). There is insufficient antecedent basis for this limitation in the claim. More specifically, the claims have been amended to recite in step (a) that "at least one withdrawing group", however if there is more than one group, it would be unclear to what specific group

Art Unit: 1632

would be referred, or if it encompasses other withdrawing groups that may present in molecules that were covalently bonded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11, 19-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pierce catalog as evidenced by Arpicco *et al.*

Applicants note the embodiments of the amendments to claims 7 and 19, and argue that the compounds taught in the Pierce catalog fail to meet the limitation that the withdrawing group is different from the two reactive groups. See Applicants' amendment, page 5. Applicants' arguments have been fully considered, but not found persuasive.

At issue appears to be the interpretation of the breadth of the instant claims. It is noted that the claims are directed to a composition and set forth as a product by process, however the product produced by the process is extremely large encompassing effectively anything with a labile disulfide that is cleaved more rapidly than glutathione and wherein upon cleavage of the disulfide two molecules would result. Step (b) of claims 7 and 19 infer that the "reactive groups" are used to used to form covalent bounds with two separate molecules on each side of the disulfide, however what molecules are reacted and what results as a final product is not

Art Unit: 1632

specifically defined by this process, except with respect to the remaining disulfide bond. After making the product by process, what is at either side of the disulfide still encompasses the presence of “reactive groups”, and these can be electron withdrawing groups as well. The guidance at pages 5-7 provide a description of the cross-linker without any specific guidance to the process used to make the cross-linker, or how the cross-linker is subsequently used to make a composition as now claimed. The broadest reasonable interpretation of the composition encompassed by the claim given the guidance of the specification is the set forth in the formula of: A1-S-S-A2

where the groups encompassed by A serve to lower the pKa of the constituent thiols (pages 4-5), and further that the groups that do this are electron withdrawing groups (general guidance given on pages 5-on-but no necessarily limited to the specific examples). The broadest reasonable interpretation of the composition(s) encompassed by the claims is any compound that has a disulfide that is cleaved more rapidly than glutathione and results in two molecules. The molecules that are added or modified can be essentially anything, as long as they result in the final product having the functional properties claimed. Applicants have not refuted that the cross-linkers have the functional property, only that it is potentially lost if it is reacted with other molecules that would not be electron withdrawing. However, the claimed product must be interpreted as a product obtained by any means, and given its broadest reasonable interpretation for the breadth the claims encompass. In this case, as discussed before, while the method steps are active “forming” steps, a reasonable interpretation of the breadth of the claims is that the composition must simply comprise the labile disulfide, conforming with the R-S-S-R formulation, and meet the functional limitations required by the claims. Finally it is noted that

Art Unit: 1632

the compounds on page T-172 of the Pierce catalog all contain two reactive groups at either end, and at least a amine (see DPDPB or sulfo-LC-SMPT) or a carbonyl which would be considered an electron withdrawing group. So even if the compounds are reacted with one or more additional molecules as indicted by its applications/references, the presence of an amine or =O would meet the limitations of claims given the guidance of the present specification.

The Pierce catalog discloses multiple bi-functional and hetero-bi-functional cross linkers that contain disulfide bonds (pages T-157-T-200). As evidence by Arpicco *et al.* the disulfide bonds of these compounds are more labile and are cleaved more rapidly than glutathione. In light of the minimum requirement that the claimed composition must have a di-sulfide bond that is cleaved more rapidly than glutathione and any other chemical on either side that does not affect this cleavage rate, the hetero-bi-functional cross-linkers anticipate the claims. Since the compounds disclosed by Pierce were synthesized, and thus imply reactable groups were present, they meet the limitations of the claim to encompass reacted groups. As stated previously, assessing what is required and encompassed by the present independent claims it appears that all that is required is a compound with a di-sulfide bond that is cleaved more rapidly than oxidized glutathione. The exact nature of the chemical composition on either side of the di-sulfide bond is broad, but is being interpreted to encompass at least anything that does not affect the ability of the di-sulfide bond to be cleaved more rapidly than glutathione.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is

Art Unit: 1632

appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-11 and 19-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of US Patent 6,936,729 (previously set forth over claims 1, 3, 6-8, 10, 11, 19 and 20 of U.S. Patent Application No. 09/75,607).

Applicants note that the instant application and issued patent are related, and both reference the same provisional application 60/085,746, filed May 16, 1998. Applicants note that an improper extension of time can not occur in this situation. See Applicants' amendment, page 5. Applicants' arguments have been fully considered, but not found persuasive.

Examiner acknowledges that the instant application and issued patent each reference the same provisional application 60/085,746, however an improper extension of time is only one possible aspect noted in the basis of the double patenting rejection. A second issue noted above is "to prevent possible harassment by multiple assignees". A terminal disclaimer is appropriate when two separate patents are to be issued with overlapping claim embodiments to very similar inventions.. Effectively, this is an indication that the claims of a given application are directed to the same invention of that found in another application/patent.

Art Unit: 1632

As noted previously, although the conflicting claims are not identical, they are not patentably distinct from each other because encompass a complex that comprises a disulfide bond that has a lower thiol pKa than glutathione thiol pKa when measured under the same conditions. Dependent claims set forth the same limitations for the polymer, and that it is capable of attack from a free thiol. The intended use for comprising another ligand in the polymer structure, or for the use of delivering a nucleic acid are contemplated and obvious additions to that are encompassed by the composition set forth as a product by process in the instant application.

Conclusion

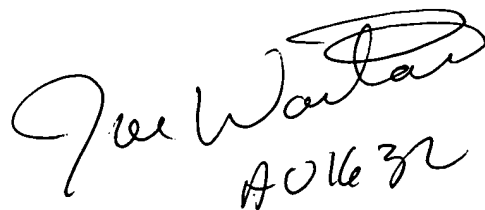
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



Joe Woitach
A01632